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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Penfold	
Application No.: 09/557,955	Group Art Unit: 1645
Filed: 4/25/2000	Examiner: Patricia Ann Duffy
Title: Assay Reagents and Devices	Confirmation No: 8900
Attorney Docket No.: IMIN.P-027	
Customer No.: 021121	

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF APPEAL BRIEF

Dear Sir:

In support of the Appeal in the above-captioned matter, Applicants enclose the following papers:

Brief for Appellant, in triplicate
an Amendment After Appeal, and
a Credit Card Payment form for the fee for submission of the brief and an extension of time.

An extension of time sufficient to make this filing timely is requested. The Commissioner is authorized to charge any additional fees or credit any overpayment to Deposit Account No. 15-0610.

Respectfully Submitted,

Marina T. Larson

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I hereby certify that this paper and any attachments named herein are being deposited with the US Postal Service as first-class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on March 3, 2004.

Marina T. Larson

Marina T. Larson, PTO Reg. No. 32,038

March 3, 2004
Date of Signature

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BRIEF FOR APPELLANT

This brief is filed in support of Applicants' Appeal from the final rejection mailed 3/27/2003. Consideration of the application and reversal of the rejections are respectfully urged.

Real Party in Interest

The real party in interest is Inverness Medical Switzerland, GmbH.

Related Appeals and Interferences

To Applicants' knowledge, there are no related appeals or interferences.

Status of Claims

Claims 2-11 are rejected. Claims 12-20 are allowed. Claim 1 has been cancelled. No other claims have been presented in this application.

Status of Amendments

The Examiner refused entry of the amendments filed October 3, 2003 and October 23, 2003. The claims in the appendix do not include the amendment proposed in these papers. A third amendment after final that merely corrects a grammatical error in claims 7 and 8, a grammatical error which was not a basis for any of the outstanding rejections, is filed herewith. This amendment should be entered, and is reflected in the claims of the appendix.

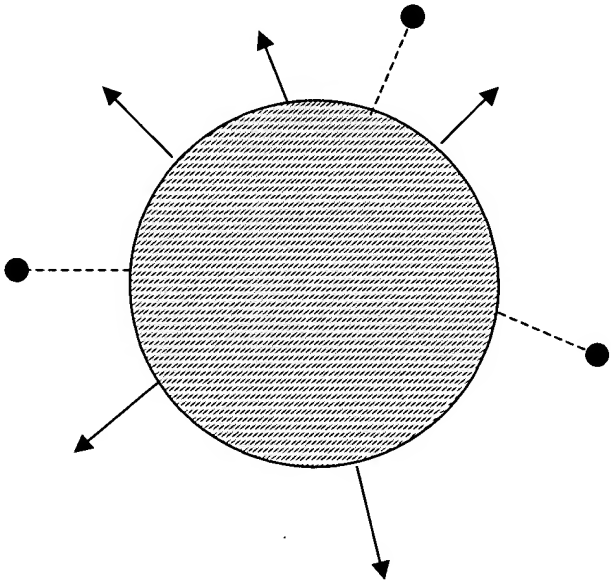
Summary of Invention

The present application relates to an assay device of a type that can be used, by way of example, in a pregnancy test. Devices of this general type are not new, and claim 9 is therefore presented in Jepson format in independent claim 9, as an improvement to "an assay device wherein a sample liquid reconstitutes a labelled reagent and carries it into a detection zone and a control zone, binding of said labelled reagent in these zones revealing the assay result." As set forth in claim 9, the improvement of the present invention is the use of a labelled reagent that comprises a particulate direct label co-sensitised with two materials:

(i) a first specific binding agent having specificity for the analyte to be detected, and

(ii) a non-specific protein which can participate in a control reaction with another specific binding agent which does not bind to said first specific binding agent nor participate in the formation of a complex by means of which detection of said analyte is accomplished in said detection zone.

Thus the labelled reagent can be depicted graphically as a colored particle with two types of binding reagents (---● and ——►) on it:



Issues on Appeal

1. Whether the claims are definite so as to meet the requirements of 35 USC § 112, second paragraph?

2. Must the preamble of a Jepson claim be considered in assessing the scope of a claim for purposes of assessing patentability over the art?

3. When claims 5, 9, 10 and 11 are properly considered as a whole, are they patentable over the May reference cited in the anticipation rejection?

Applicants submit that all of these questions should be answered in the affirmative.

Grouping of Claims

With respect to claim 5, 6, 7 and 8 which have separate grounds for rejection applied to them under 35 USC § 112, these claims are argued separately and do not stand or fall together. These grounds do not apply to other claims, and these claims do not stand or fall with the decision on these rejections. With respect to the general § 112 rejection, the claims are argued together, and stand or fall as a group.

The second issue on appeal relates to all of claims 5, 9, 10 and 11 rejected for anticipation, and the claims are argued as one group.

With respect to the third issue, claims 5, 9, 10 and 11 are each argued separately, and do not stand or fall together.

Argument

Claims 2-11 Meet the Definiteness Requirement of 35 USC § 112, Second Paragraph.

Claims 2-11 stand rejected for lack of compliance with the definiteness requirement of 35 USC § 112, second paragraph. The reasons given for this rejection, are several. However, Applicants submit that all of the rejections are in error.

In the Office Action of March 27, 2003, the Examiner states that claim 9 and the claims dependent thereon are indefinite "because it is unclear if the claim is directed to an assay device, a process for assaying or a particulate reagent." The basis for this position taken by the Examiner is unclear. Claim 9 starts with the words **"In an assay device."** Each of the dependent claims refers to "The assay device " of a preceding claim. There is no reason that a person skilled in the art would be confused as the examiner argues. Thus, this rejection to the extent it depends on this argument should be reversed.

The Examiner also states that Claim 9 is confusing because it refers to a second reagent that "can participate" in a control reaction as opposed to one that is bound in a control reaction. Applicants point out, however, that such binding only occurs when the device is in use, that is after a sample has been applied. The claim is directed to an assay device as it would be provided for use in testing. At this time, the labelled reagent has not yet been carried into the detection and control zones (an event which occurs when the device is used) and therefore the control reaction has not occurred, it is a reaction that **can occur** because of the binding specificity. The claim therefore is not indefinite, and this rejection to the extent it depends on this argument should be reversed.

The Examiner argues that claim 9 is indefinite because it is not in compliance with 37 CFR § 1.75(e). Whether or not this is a valid basis for a rejection under 35 USC § 112, second paragraph, the Examiner's position is plainly in error. 37 CFR § 1.75(e) says that an independent claim to an improvement may start with "a preamble comprising a general description of all the elements or steps of the claimed combination which are known or conventional." In claim 9, this part of the claim is as follows:

> **In an assay device wherein a sample liquid reconstitutes a labelled reagent and carries it into a detection zone and a control zone, binding of said labelled reagent in these zones revealing the assay result...**

The rule continues by stating that the claim shall include "a phrase such as "wherein the improvement comprises." In claim 9, this part of the claim is found in the phrase

> **... the improvement wherein ...**

Finally, the rule states that the claim shall set forth "those elements, steps, and/or relationships which constitute that portion of the claimed combination which the applicant considers as the new and improved portion." In claim 9, this part of the claim reads as follows:

> **...said labelled reagent comprises a particulate direct label co-sensitised with**
>
> **(i) a first specific binding agent having specificity for an analyte, and**
>
> **(ii) a non-specific protein which participates in a control reaction with another specific binding agent which does not bind to said first specific binding agent nor participate in the formation of a complex by means of which detection of said analyte is accomplished in said detection zone.**

The Examiner has never stated what part of the requirements of the rule is supposedly missing, and it is clear that there is nothing missing. The § 112 rejection to the extent it depends on this argument should be reversed.

The Examiner states that claim 5 is indefinite because "it is unclear if the recitation is admitted prior art" as it relates to the preamble, or is meant to reconstruct the direct particulate label of the Jepson claim. This rejection is not understood, nor has the Examiner's statement of the rejection offered any reason why a person skilled in the art would fail to understand the scope of the claim. Claim 5 reads:

> An assay device according to claim 9, additionally comprising a second population of direct particulate label sensitised solely with said non-specific protein.

The plain meaning of this claim is that the device that is being claimed includes a second population of direct particulate labels that have different properties than the direct particulate labels already referenced in the claims. It is not the same particulate label defined in claim 9 because it only has the one sensitizing reagent, but it does include the same non-specific protein as the particulate labels described in claim 9. Since all that is required of a claim for compliance with § 112, second paragraph is the ability to understand what is being claimed, a requirement which claim 5 meets; and since the burden is on the Examiner to explain why a person skilled in

the art would not understand the claim scope,[1] the rejection of claim 5 on this basis should be reversed.

The Examiner states that claim 6 is indefinite because "it is unclear what limitation is applied to what portion of the particulate label in claim 9." The Examiner also states that claim 6 lacks an antecedent basis, although the reason for this statement is not given. Claim 6 as now pending, reads as follows:

> An assay device according to claim 2, wherein the particulate direct label comprises a first set of coloured latex particles of diameter less than 0.5 micron, co-sensitised with an anti-hCG murine monoclonal antibody and with rabbit IgG.

It appears that the Examiner complaint is that the claim does not specifically spell out that the anti-hCG monoclonal antibody corresponds to the first specific binding reagent and that the rabbit IgG corresponds to the second binding reagent. While Applicants attempted to add the language specifically suggested in the two refused amendments after final, the fact is that **for a person skilled in the art**, there is no lack of definiteness in the claim as now pending. Thus, the rejection of claim 6 on this ground should be reversed.

Claims 7 and 8 stand rejected because "it is unclear if the limitation is admitted prior art or not, or how it limits the independent Jepson claim in a Jepson format." Again, Applicants ask what legal basis there is for requiring an identification of whether or not the limitation is admitted prior art? The Examiner has cited none, and this seems to have no bearing on an understanding of the scope of the claims.

Claim 7 reads as follows:

> An assay device according to claim 6, additionally comprising a second set of coloured latex particles of the same colour as the first set of coloured latex particles and of diameter less than 0.5 micron sensitised solely with rabbit IgG, the ratio of said first particles to said second particles being at least 2:1.

Taken together with claim 6, this reads:

---

[1] It is noted that the Examiner seems to be hypertechnical about the Jepson format requirements, while offering o legal basis for the arguments. It is also noted that a person skilled in the art would not necessarily know of these technicalities anyway, and would just read the claim in plain English. Applying this standard, the claim is clear and definite.

An assay device according to claim 2, wherein the particulate direct label comprises a first set of coloured latex particles of diameter less than 0.5 micron, co-sensitised with an anti-hCG murine monoclonal antibody and with rabbit IgG, and additionally comprising a second set of coloured latex particles of the same colour as the first set of coloured latex particles and of diameter less than 0.5 micron sensitised solely with rabbit IgG, the ratio of said first particles to said second particles being at least 2:1.

There is no question that these claims, taken together define the nature of the particulate direct label, as recited in claims 9 and 2, and the presence in a assay device of a second set of labels that is not co-sensitized. The Examiner has not stated how this would not be understood, and indeed, from the statement in the Official Action on Page 3, seems to have had no difficulty understanding the claim. Thus, this aspect of the rejection should be withdrawn.

The Examiner also states that claim 8 does not have clear antecedent basis in claim 7. Claim 8 reads:

8. An assay device according to claim 7, wherein said ratio is about 3:1.

The only ratio in any preceding claim is the ratio in claim 7. Thus, there is antecedent basis for claim 7, and no possible ambiguity. Thus, the basis for the Examiner's position is unclear, and the rejection should be reversed.

The Examiner rejected claims 5, 9, 10 and 11 as anticipated under 35 USC § 102(e) by US Patent No. 5,662,871 of May et al. Central to this rejection is the Examiner's unsupported assertion that in considering the patentability of a Jepson format claim, the preamble is ignored and that only the limitations considered to be new are compared to the art. This is legally improper. A Jepson claim recites a combination of all of the elements in the claim, both those in the preamble and those in the body of the claim. *Pentec, Inc. v. Graphic Controls, Corp.*, 776 F.2d 309, 315, 227 USPQ 766, 770 (Fed. Cir. 1985) ("Although a preamble is impliedly admitted to be prior art when a Jepson claim is used, . . . the claimed invention consists of the preamble in combination with the improvement."). It is this combination that is the claimed invention, and it is this combination that must be found in a single prior art reference, not just the "improvement" taken in isolation.

Furthermore, the disclosure of May is unable to support an anticipation rejection. The Examiner has argued that the Examiner asserts that May et al "disclose an assay device

wherein a particulate direct label is sensitized with a specific binding agent and a non-specific protein to form a complex which can be detected." The Examiner has pointed to Col. 16, lines 34-57 as teaching a particulate direct label which has an antibody specific binding reagent, and bovine serum albumin (BSA) which the Examiner characterizes as the non-specific protein. The BSA in May serves solely as a blocking agent, and is not involved in any binding reaction within the device as therein described. Thus, the BSA is not a non-specific protein which can participate in the control reaction in the device of May, and there is no anticipation.

Furthermore, Applicants note that the anticipation rejection is, by the Examiner's own words, predicated on the Jepson format of the claim, and the Examiner's erroneous beliefs that the preamble does not limit the claims and is not relevant in assessing patentablity . Indeed, the Examiner expressly refused to consider the limitations of claims 5, 10 and 11 in making the anticipation rejection because they did not relate to the co-sensitized particulate label. The limitations of these claims are not found in the May reference. Accordingly, the rejection of these claims for anticipation is based solely on the Examiner's legal error and must be reversed.

Specifically, claim 5 contains the limitation that the device "additionally compris[es] a second population of direct particulate label sensitised solely with said non-specific protein." There is no teaching in May of such a second population of particulate labels. Thus, this claim is not anticipated.

Claim 10 states that wherein "said detection zone contains an immobilised specific binding agent which acts as a direct or indirect capture means for said analyte but which does not bind to said non-specific protein, and said control zone contains a specific binding agent which binds said non-specific protein but does not bind said specific binding agent co-sensitised on said particulate direct label." May does not disclose a control zone with a binding agent specific to BSA. Thus, this claim is not anticipated.

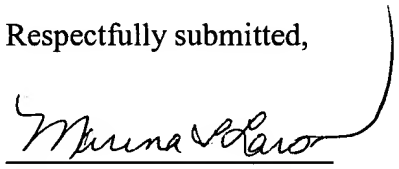
Claim 11 adds the further limitation that "said detection zone contains an immobilised specific bind agent which acts as a direct or indirect capture means for hCG, said control zone contains an immobilised anti-rabbit IgG antibody, and said labelled reagent is coloured latex particles of diameter less than 0.5 micron, co-sensitised with an anti-hCG murine monoclonal antibody and with rabbit IgG." Plainly, a particle having an antibody and BSA is not

equivalent to a particle having an antibody (in this case specifically anti-hCG) and rabbit IgG. Furthermore, BSA would not be captured by anti-rabbit IgG, and there is no teaching of a control zone containing anti-rabbit IgG in May. Thus, for many reasons, this claim is not anticipated by the May reference.

Conclusion

For these reasons, Applicants submit that this application is allowable, and that the outstanding rejections should all be reversed.

Respectfully submitted,



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CLAIMS ON APPEAL

2. An assay device according to claim 9, wherein said first specific binding agent is an antibody raised in a first species and said non-specific protein is an immunoglobulin from another species.

3. An assay device according to claim 9, wherein said first specific binding agent is a murine antibody.

4. An assay device according to claim 2, wherein said non-specific protein is a rabbit immunoglobulin.

5. An assay device according to claim 9, additionally comprising a second population of direct particulate label sensitised solely with said non-specific protein.

6. (with pending amendment shown) An assay device according to claim 2, wherein the particulate direct label comprises a set of first coloured latex particles of diameter less than 0.5 micron, co-sensitised with an anti-hCG murine monoclonal antibody and with rabbit IgG.

7. (with pending amendment shown) An assay device according to claim 6, additionally comprising a second set of coloured latex particles of the same colour as the first set of coloured latex particles and of diameter less than 0.5 micron sensitised solely with rabbit IgG, the ratio of said first particles to said second particles being at least 2:1.

8. An assay device according to claim 7, wherein said ratio is about 3:1.

9. In an assay device wherein a sample liquid reconstitutes a labelled reagent and carries it into a detection zone and a control zone, binding of said labelled reagent in these zones revealing the assay result, the improvement wherein said labelled reagent comprises a particulate direct label co-sensitised with

(i) a first specific binding agent having specificity for an analyte, and

(ii) a non-specific protein which participates in a control reaction with another specific binding agent which does not bind to said first specific binding agent nor participate in the formation of a complex by means of which detection of said analyte is accomplished in said detection zone.

10. An assay device according to claim 9, wherein said detection zone contains an immobilised specific binding agent which acts as a direct or indirect capture means for said analyte but which does not bind to said non-specific protein, and said control zone contains a specific binding agent which binds said non-specific protein but does not bind said specific binding agent co-sensitised on said particulate direct label.

11. An assay device according to claim 9, wherein said detection zone contains an immobilised specific bind agent which acts as a direct or indirect capture means for hCG, said control zone contains an immobilised anti-rabbit IgG antibody, and said labelled reagent is coloured latex particles of diameter less than 0.5 micron, co-sensitised with an anti-hCG murine monoclonal antibody and with rabbit IgG.